HEALTH AND SENIOR SERVICES

OFFICE OF LEGAL AND REGULATORY AFFAIRS

Interchangeable Drug Products

Proposed Readoption with Amendment: N.J.A.C. 8:71-1

Authorized By: _____

Clifton R. Lacy, M.D., Commissioner, Department of Health and Senior Services, as successor to the functions of the Drug Utilization Review Council.

Authority: The Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., particularly 24:6E-6(b); and P.L. 2003, c.122 (July 1, 2003); N.J.S.A. 26:1A-15.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2004- .

Submit written comments by 2004 to:

Jay Hedden, Deputy Director

Department of Health and Senior Services

Office of Legal and Regulatory Affairs

PO Box 360

Trenton, NJ 08625-0360

Telefacsimile: (609) 984-5474

The agency proposal follows:

Summary

N.J.A.C. 8:71, Interchangeable Drug Products, establishes the list of interchangeable drug products the Drug Utilization Review Council is required to promulgate pursuant to the Prescription Drug Price and Quality Stabilization Act, N.J.S.A. 24:6E-1 et seq., particularly 24:6E-6(b). N.J.S.A. 24:6E-4*l* defines "Interchangeable drug products" as pharmaceutical equivalents or bioequivalents that are determined to be therapeutic equivalents by the Council. N.J.S.A. 24:6E-4h defines "Therapeutic equivalents" as chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy or toxicity as their respective reference drug products. Interchangeable drug products are commonly referred to as "generic" drugs in the sense that they can take the place of brand-name drugs.

N.J.S.A. 24:6E-7 requires New Jersey pharmacists to substitute automatically a drug product from the list of interchangeable drug products provided at N.J.A.C. 8:71 for a prescribed brand name drug product, unless the prescriber specifically indicates that substitution is impermissible, and subject to the exercise of the pharmacist's professional judgment as specified at N.J.S.A. 24:6E-8.

N.J.A.C. 8:71 is scheduled to expire on November 13, 2004.

The Fiscal Year 2004 Appropriations Act, P.L. 2003, c.122, approved July 1, 2003, provides: "Notwithstanding the provisions of any law or regulation to the contrary, effective July 1, 2003, no state funds are appropriated for a Drug Utilization Review Council in the Department of Health and Senior Services and therefore the functions of the Council shall cease."

Notwithstanding the cessation of the functions of the Drug Utilization Review Council, the continued existence of the list of interchangeable drug products remains necessary to the routine operation of pharmaceutical dispensing of drugs in this State and the ability of pharmacists to comply with N.J.S.A. 24:6E-1 et seq.

Pursuant to the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. § 355(j)(7), the Secretary of the United States Department of Health and Human Services, through the Office of Generic Drugs in the Office of Pharmaceutical Science of the Center for Drug Evaluation and Research of the United States Food and Drug Administration (FDA) produces a list of "Approved Drug Products with Therapeutic Equivalence Evaluations" commonly known as the "Orange Book." The Orange Book (hereinafter also referred to as the "Federal formulary") functions as the Federal equivalent of the list of interchangeable drug products provided at N.J.A.C. 8:71 (hereinafter also referred to as the "State formulary"). The FDA updates the Orange Book monthly. The monthly update of the Orange Book is timelier than the process used by the Drug Utilization Review Council to update the State formulary. As compared with the FDA's monthly process, it takes several months to add new generic products to the State formulary.

The Department has determined to amend N.J.A.C. 8:71 to incorporate by reference, as amended and supplemented, the Orange Book to serve as the functional equivalent of the list of interchangeable drug products the Drug Utilization Review Council is required to promulgate for the effectuation of N.J.S.A. 24:6E-1 et seq. The existing State formulary currently lists drug products that the Orange Book does not list. Therefore, the Department has determined to maintain the existing State formulary and

to amend it as N.J.A.C. 8:71-1.1(b). The Department would incorporate the Orange Book by reference, as amended and supplemented, at new N.J.A.C. 8:71-1.1(c).

Proposed new N.J.A.C. 8:71-1.1(a) would articulate the operation and precedence of the lists. The two lists would operate concurrently. In the event a drug product appears on one of either the State or Federal formularies, the drug product would be an interchangeable drug product within the meaning of N.J.S.A. 24:6E-1 et seq., except in the situation where a drug product formerly appeared on the Orange Book formulary but was removed by action of the FDA, in which case the Federal formulary would control.

The Department does not intend the concurrent existence of these two formularies to operate indefinitely. The Department is proposing this measure as a stopgap until the Department is able to meet and work with the regulated community to develop a policy to address concerns relating to inconsistencies between the two formularies, or until the Orange Book "catches up" to the State formulary by the addition of drug products to the Federal formulary that already appear on the State formulary. The Department anticipates that the mediation process will take approximately one year.

The Department intends eventually to repeal the State formulary and to designate the Orange Book as the exclusive list of interchangeable drug products required by N.J.S.A. 24:6E-1 et seq. At that time, a party who wishes to obtain approval for a drug product as an interchangeable drug product would have to petition the FDA for that drug product's inclusion in the Federal formulary. In the meantime, the Department proposes to readopt existing N.J.A.C. 8:71 and to amend it as described

above to maintain the continued effectiveness of the State formulary until the Department is able to develop an approach to resolve conflicts between the two formularies, or until the Orange Book "catches up" to the State formulary.

Therefore, in accordance with N.J.A.C. 52:14B-5.1 and Executive Order No. 66 (Byrne 1978), the Commissioner, as successor to the powers of the Drug Utilization Review Council, has determined that N.J.A.C. 8:71, as proposed to be amended in the manner and for the reasons described above, is necessary, adequate, reasonable, efficient, understandable, and responsive to the purposes for which it was promulgated.

A 60-day comment period is provided for this notice of proposal, and, therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, the proposal is not subject to the provisions of N.J.A.C. 1:30-3.1 and 3.2 governing rulemaking calendars.

Social Impact

The rule proposed for readoption and amendment would permit the continued routine pharmaceutical dispensing of interchangeable drug products in this State and would enable pharmacists to continue to comply with N.J.S.A. 24:6E-1 et seq., while at the same time responding to the cessation of the functioning of the Drug Utilization Review Council. The continued existence of N.J.A.C. 8:71, as proposed to be readopted and, amended by the incorporation by reference of the Orange Book, as amended and supplemented, would enhance the ability of pharmacists to dispense, and New Jersey consumers of drug products to obtain, interchangeable drug products as soon as the FDA approves the drug products as safe and effective for inclusion in the Orange Book. Inasmuch as the FDA updates the Orange Book more frequently and promptly than the Drug Utilization Review Council was able to update the State

formulary, the rule proposed for readoption and the proposed recodification and amendment would make these drug products available to consumers sooner.

Economic Impact

The rule proposed for readoption and amendment will have a positive economic impact on New Jersey consumers of drug products and entities such as employers and other entities who provide or pay for prescription drug plans, by allowing timely updates to the list of interchangeable drug products, thereby permitting enhanced and faster access to generic drug products. Generic drug products are generally less expensive than brand name equivalents. Pharmacists may be able to save money in drug product inventory investment, and may in turn pass on their overhead and cost savings to New Jersey drug product consumers and other entities such as employers and other entities that provide or pay for prescription drug plans.

The rule proposed for readoption and the proposed recodification and amendment may have an indirect positive economic impact on the taxpayers of New Jersey. Taxpayer-funded programs, such as Pharmaceutical Assistance to the Aged and Disabled (PAAD), Medicaid, and prescription drug insurance programs made available to public employees, would continue to realize a savings by the continued availability of interchangeable drug products.

Failure to readopt the chapter and to provide an alternative to the functions of the Drug Utilization Review Council through the adoption of the Orange Book would make it impossible for New Jersey pharmacists to comply with N.J.S.A. 24:6E-1 et seq., in that there would be no list for them to refer to in complying with their obligation to substitute

cheaper, but therapeutically equivalent, “generic” drug products for more expensive brand name drug products. In addition, failure would make it harder, if not impossible, for New Jersey drug product consumers to obtain less expensive interchangeable drugs as they become available and approved for use. This would have a detrimental effect on persons of limited or fixed incomes, such as seniors, who depend on the availability of generic drugs to maintain their health within the constraints of their financial means.

Federal Standards Statement

A Federal standards analysis is not required because the rule proposed for readoption and amendment are not subject to any Federal requirements or standards. The Department has elected to incorporate by reference, as amended and supplemented, the list of “Approved Drug Products with Therapeutic Equivalence Evaluations” commonly known as the “Orange Book,” promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. § 355(j)(7), by the Secretary of the United States Department of Health and Human Services, through the Office of Generic Drugs in the Office of Pharmaceutical Science of the Center for Drug Evaluation and Research of the United States Food and Drug Administration (FDA), to serve as the list of interchangeable drug products that N.J.S.A. 24:6E-1 et seq. requires to be promulgated. The State’s determination to rely on the Orange Book as the list of interchangeable drug products that N.J.S.A. 24:6E-1 et seq. requires the State to promulgate is not required under any Federal mandate. As discussed in the Summary, above, the Department intends eventually to repeal the State formulary entirely and to rely solely on the Federal formulary as the list of interchangeable drug products that N.J.S.A. 24:6E-1 et seq. requires to be promulgated.

Jobs Impact

The Department does not anticipate that adoption of the rule proposed for readoption and amendment would have an impact on jobs. The cessation of the Drug Utilization Review Council occurs by operation P.L. 2003, c.122 (July 1, 2003). Members of the Drug Utilization Review Council serve either *ex officio* or by voluntary appointment and without compensation, pursuant to N.J.S.A. 24:6E-5.

Failure to adopt the rule proposed for readoption and the proposed recodification and amendment may have an impact on jobs in New Jersey. A number of pharmaceutical companies are located in New Jersey, some of which may develop and manufacture generic drug products that would appear on the list of interchangeable drug products. The unavailability of a list of interchangeable drug products may reduce the demand for generic drug products, which in turn may reduce the demand for workers in the generic drug development and manufacturing industry.

Agriculture Industry Impact

The Department does not believe that the rule proposed for readoption and amendment would have any impact on the agriculture industry in the State, beyond providing a list of generic drugs that veterinarians may substitute for brand-name drugs in the practice of veterinary medicine. The primary purpose of the chapter is to provide a list of interchangeable drugs that can be substituted for brand-name drugs for use by humans.

Regulatory Flexibility Statement

A regulatory flexibility analysis is not required because the rule proposed for readoption and amendment does not impose any recordkeeping, reporting or other requirements on any "small businesses" as defined in the Regulatory Flexibility Act at N.J.S.A. 52:14B-16 et seq.

To the extent New Jersey pharmacists may be "small businesses" within the meaning of the Regulatory Flexibility Act at N.J.S.A. 52:14B-16 et seq., N.J.S.A. 24:6E-7 requires New Jersey pharmacists to substitute automatically a drug product from the list of interchangeable drug products for a prescribed brand name drug product, unless the prescriber specifically indicates that substitution is impermissible, and subject to the exercise of the pharmacist's professional judgment as specified at N.J.S.A. 24:6E-8. The rule proposed for readoption and amendment at N.J.A.C. 8:71 would not impose this requirement; N.J.A.C. 8:71 as proposed to be readopted and amended would provide the list that enables pharmacists to comply with their obligation under the statute.

Smart Growth Impact

The rule proposed for readoption and amendment would have no impact on the achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Full text of the proposed readoption can be found in the New Jersey Administrative Code at N.J.A.C. 8:71.

Full text of the proposed recodification and amendment follows (additions in boldface thus; deletions in brackets [thus]):

CHAPTER 71

INTERCHANGEABLE DRUG PRODUCTS

SUBCHAPTER 1. LISTS OF INTERCHANGEABLE DRUG PRODUCTS

8:71-1.1 Precedence of lists

(a) A drug product that appears on one of the lists provided at either (b) or (c) below, shall be an interchangeable drug product as that term is defined at N.J.S.A. 24:6E-1 et seq. If a drug product that appears on the list at (b) below is banned from use by action of the Food and Drug Administration of the United States Department of Health and Human Services, then only the list provided in (c) shall be used.

(b) The following drugs are listed alphabetically, in a format [which] that represents the name of the substituted brand name drug (reference drug), the generic name of the drug product, the strength and dosage delivery system of the drug products, and the names of the approved generic drug's manufacturers.

ACCUPRIL

…

ZYLOPRIM

…

(c) Drug products identified in the publication of the Office of Generic Drugs in the Office of Pharmaceutical Science of the Center for Drug Evaluation and Research of the Food and Drug Administration of the United States Department of Health and Human Services, "Approved Drug Products with Therapeutic Equivalence Evaluations," 24th Edition, incorporated herein by reference, as amended and supplemented, commonly known as the "Orange Book," promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, at 21 U.S.C. § 355(j)(7), shall serve as the list of interchangeable drug products required by N.J.S.A. 24:6E-1 et seq. The Orange Book can be obtained by contacting the Superintendent of Documents, Government Printing Office, P O Box 371954, Pittsburgh, PA 15250-7954, (202) 512-1800 or toll free (866) 512-1800, and is available on-line at http://www.fda.gov/cder/orange/default.htm and at http://www.fda.gov/cder/ob/default.htm.